



Poly-XV^E™ Technical Paper

Highly Crosslinked and Vitamin E Stabilized UHMWPE

Robert A. Poggie, PhD
President, BioVera, Inc.





Our History

BioMedtrix was founded in 1989 with the objective of designing, developing, and manufacturing state-of-the-art veterinary orthopedic implants. Our continuing mission is to provide quality in all aspects of product development, manufacturing, and customer service. Through research sponsorships and collaborations with the world's foremost surgeons, BioMedtrix continues to support the development of new programs to address veterinary needs.

BioMedtrix is represented in more than 95% of US veterinary teaching universities, selected international universities, and specialty clinics throughout the world. We have over 400 clients in more than 40 countries, many of whom have been using BioMedtrix products for over 30 years. This level of support from our customers provides BioMedtrix the opportunity to continue product innovation and development.

Research and Development

With over 36 years of development experience in human and veterinary implants, BioMedtrix has developed proprietary processes, and patented several designs that address clinical needs in the canine hip, knee, elbow, ankle, and trauma fields of orthopaedics. Our research and testing approaches have demonstrated improved product development cycles with designs that promote long-term mobility.

Quality

BioMedtrix operational policies maintain quality standards comparable to those used by human orthopedic manufacturers. We adhere to all ASTM specifications for implant materials and maintain standards for articulating surfaces of implants which meet or exceed those specified for human implants.

Advisory Program

BioMedtrix maintains relationships with key veterinarians who provide technical and clinical feedback, as well as guidance on product development. These surgeons are specialists in veterinary orthopedics and cumulatively have over 250 years of experience in veterinary medicine.

biomedtrix.com



History of highly cross-linked polyethylene and vitamin E stabilization

Ultra-high molecular weight polyethylene (UHMWPE) has been the material of choice for bearing components in joint arthroplasty implants since the early 1960's, with its introduction by Dr. John Charnley. However, long-term wear of UHMWPE and the resulting wear debris is the number one cause of peri-prosthetic osteolysis in human total joint replacements (TJR) [1-7]. In an attempt to mitigate polyethylene wear, highly crosslinked polyethylene (HCLPE) was developed in the late 1990s to decrease wear and increase longevity of TJR devices. HCLPE is a modified form of UHMWPE that has a higher crosslink density that is realized through irradiation above that necessary for sterility assurance. A gamma radiation dose range of 25-40 kGy is typical for sterilization processing, while 75 to 130 kGy is the range for HCLPE. The radiation energy cleaves UHMWPE molecules that produce free radicals that can in turn cross-link with neighboring UHMWPE molecular chains [8-10]. However, the residual free radicals in the crystalline phase of HCLPE can react with oxygen which in turn causes oxidative embrittlement, which reduces resistance to wear

and degrades mechanical properties. Also dating back to the late 1990s and 2000s, several elevated temperature processes were applied to HCLPE materials, with the aims of enhancing crosslinking and reducing oxidation. However, several of these methods were later observed to degrade the properties and compromise the performance of HCLPE materials over the long term.

Because of oxidative degradation, UHMWPE research in the 2000s focused on processing and additive means to reduce or prohibit oxidation during and after crosslinking. Beginning in 2005 with a Biomet acetabular implant (FDA clearance # K050327), vitamin E (α -tocopherol) stabilized HCLPE materials made their debut. Since then, numerous proprietary and broadly available HCLPE w/VE materials have been used to manufacture articulating surfaces in knees, ankles, and spine implants. Several examples of commercialized HCLPE w/VE materials are listed below. And the good news is that this new generation of HCLPE w/VE are withstanding the test of time via reported evidence of successful clinical use.

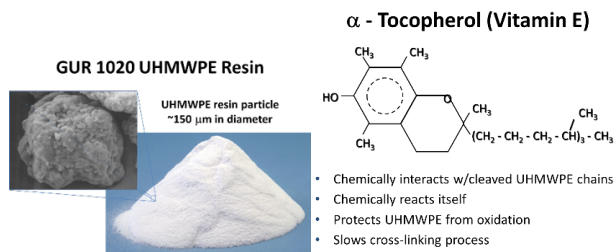
Examples of commercial brands of HCLPE for hip and knee bearings.

COMPANY	BRAND	VITAMIN E	RADIATION TYPE	STERILIZATION METHOD
Zimmer Biomet	Vivacit-E®	Yes	Gamma-Beam	Gamma-Beam
Zimmer Biomet	E1™	Yes	Gamma-Beam	Gamma-Beam
DePuy-Synthes	AOX	No; 'Covernox'	Gamma-Beam	Gas Plasma
Aesculap	Vitelene®	Yes	E-Beam	ETO
Corin	ECiMa™	Yes	Gamma-Beam	ETO
ConforMIS	ECiMa™	Yes	Gamma-Beam	Gas Plasma
Mathys	Vitamys®	Yes	Gamma-Beam	Gas Plasma
NextStep, Optimotion	VE100 kGy	Yes	Gamma-Beam	ETO
BioMedtrix	Poly-XVE™	Yes	Gamma-Beam	Gamma-Beam



Critical parameters and chemistry in manufacturing HCLPE w/VE

UHMWPE Resin, Molding, Sintering: Ultra high molecular weight polyethylene (UHMWPE) is a hydrocarbon of 2.5 to 5 million molecular weight and is supplied as a medical grade resin by Ticona, Inc. 0.1% α - Tocopherol (vitamin E) is blended into GUR 1020 resin to create Ticona's GUR 1020E. To make solid UHMWPE that can be used to make implants, the resin is molded and sintered under pressure for minutes to hours at elevated temperature. The quality of the UHMWPE depends on the process parameters and their control.



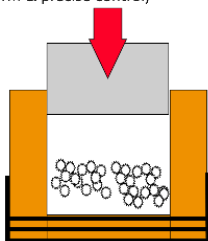
The few companies that make UHMWPE each have their own unique equipment and process parameters for time, temperature, and pressure, which in turn means that quality and performance vary from one company's material to the next. BioMedtrix has chosen Merit® UHMWPE from PPD Group, Inc. because it is the only manufacturer of small batch, direct compression molded UHMWPE with the industry's highest level of process control and quality standards. These statements have been borne out over decades of successful clinical performance in humans [32].

The below images show Merit® direct compression molded stock materials and shoulder, knee, and hip implants machined from the bar stock. The images on the right show standard UHMWPE and HCLPE w/VE knee and hip implants highlighting the yellow hue of products that are manufactured with Vitamin E containing UHMWPE. Crosslinking further accentuates the yellow hue.

Direct Compression Molding (PPD for BioMedtrix)

(small volumes are critical for uniform & precise control)

- Small volumes
 - Bar stock (2.5" diam, 16" long)
 - Plates (5" by 7" by 1")
- Low temp. gradient
- Moderate time at temperature; stable
- Reliable control of pressure

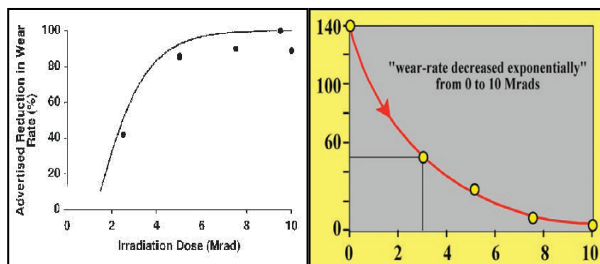


Shipped to Steris for prescribed dose of x-linking per BioMedtrix requirements.

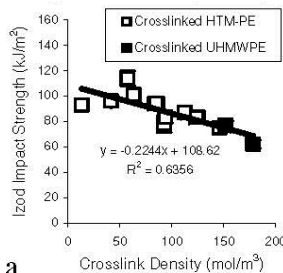




Crosslinking: Crosslinking refers to the chemical bonding of neighboring molecules of UHMWPE in a three-dimensional, dense molecular network within the amorphous regions of the material. This process can occur via chemical or ionizing radiation that cleaves UHMWPE molecules that activate the UHMWPE molecules towards cross-linking, recombination, and/or oxidation. The two methods for crosslinking orthopaedic UHMWPEs are gamma and electron beam radiation, which coincidentally are two historical methods for terminal sterilization. The primary reason for crosslinking UHMWPE is to increase resistance to wear. The tradeoffs are decreases in ductility, toughness, and resilience of UHMWPE that become clinically significant and unacceptable at radiation levels greater than 150 kGy. Because of this relationship, contemporary HCLPE materials are irradiated in a range of 75 to 130 kGy.



Decreasing hip wear with increasing radiation x-linking



a
Decreasing toughness with increasing radiation

	Toughness	Strain at failure
30 kGy	17.3	360
60 kGy	16.2	330
90 kGy	12.0	260

There have been multiple *in vitro* and *in vivo* studies that show significant increased resistance to wear of UHMWPE via cross-linking (50 – 130 kGy), ranging between 70 to 95% less wear relative to conventional UHMWPE (25-40 kGy) [21-27]. For example, a study of patients over five (5) years found the annual wear-rate of HCLPE acetabular liners to be 0.02 mm/yr, while conventional UHMWPE wore at a rate of 0.12 mm/yr [21-26]. More recent studies of thermally annealed HCLPE, that was not vitamin E stabilized, also showed a significant improvement in wear resistance over conventional UHMWPE up to 10 years [22,23], which unfortunately was followed by a rapid increase in wear through 15 years [25]. This finding has been repeated many times and in turn leading the industry towards HCLPE materials with Vitamin E.

Vitamin E (α - Tocopherol) Anti-Oxidative Additive: Currently, not all companies in the human orthopedic marketplace are using HCLPE with Vitamin E or other anti-oxidation additive; but that is changing quickly. It is probable that non-stabilized, non-crosslinked UHMWPE will be history come 2025 or thereabouts for three reasons. The first is the overwhelming laboratory evidence of reduced wear and oxidation of HCLPE w/VE, the second is the rapidly accumulating evidence of clinical success of several proprietary and more broadly available variants of HCLPE w/VE, and third is the FDA now recognizes HCLPE w/VE materials as the new 'standard', supplanting 25-40 kGy conventional UHMWPE [3,15-18].

Vitamin E stabilized UHMWPE is created by blending α - Tocopherol with GUR 1020 UHMWPE resin (0.1% by weight) to create a homogenous mixture of GUR 1020E resin that is molded, sintered, and gamma irradiation cross-linked [3,20]. The objective of fortifying UHMWPE with vitamin E is to prohibit oxidation and preserve the mechanical and wear-resistant properties of the HCLPE material.



This stabilizing effect becomes more important during and after crosslinking, and as a function of increased level of crosslinking. For example, HCLPE at 130 kGy is more susceptible to oxidation than 50 kGy material. The mechanism of action of Vitamin E within UHMWPE is relatively simple in that the α – Tocopherol molecule reacts with the activated, cleaved chains of UHMWPE (called free radicals) that did not crosslink or recombine during

radiation exposure. In other words, during and after radiation crosslinking, vitamin E effectively terminates active free radicals not already crosslinked with neighboring UHMWPE molecules. The vitamin E also combines with oxygen within the UHMWPE. Both chemical phenomena are very effective in virtually eliminating oxidation of HCLPE during and after cross-linking, and very importantly, with minimal reduction in mechanical resilience [3,7,11-14].

What is the clinical outcome in human medicine?

The HCLPE w/VE has been followed clinically since the late 2000s. Several clinical studies have documented a reduction in wear in hip and knees, with comparison to conventional polyethylene. For example, in hip clinical studies, the mean femoral head penetration rate significantly improved (0.003mm/yr.) as compared to the control conventional polyethylene group (0.051mm/yr) [3,26-31]. Below are excerpts from the concluding remarks from *six recent publications* regarding clinical outcomes with HCLPE w/VE materials [33-38].

2020 Acta Scandinavia, Goulven Rochcongar, et.al., “Wear rates continue to be lower in HXLPE/VitE cups than in UHMWPE cups at 5 years of follow-up without correlation with increasing cup inclination angles or cup sizes. Finally, HXLPE/VitE cups may have the potential to prevent osteolysis and implant loosening.”

2019 Hip International, Michael C Wyatt, et.al., “At a minimum of 3 years follow-up there was reduced total femoral head penetration for vitamin E HXLPE over HXLPE.”

2018 JBJS, G. Rochcongar, MD, et.al.: “Our results confirm that wear rates over the first 3 years following surgery were lower in HXLPE/VitE cups

than in UHMWPE cups. This suggests that HXLPE/VitE cups may prevent osteolysis, implant loosening, and eventually revision surgery.”

2018 Orthopaedic Proceedings, Malchau, et.al.: “The current study (of Vit E stabilized x-linked) is the largest analysis of polyethylene wear at five-year follow-up using RSA. We observed similar bedding in through the two-year interval between the two liner types, however, there was significantly more wear for the ModXL cohort at five-years.”

2017 JBJS, Shareghi, et.al.: “The penetration rate was higher for ArComXL (versus E1 poly), resulting in more proximal and total penetration at 5 years than for E1.”

2016 International Orthopaedics, Scemama, et.al.: “This study demonstrated that femoral head penetration was lower when using vitamin E-blended HXLPE when compared with UHMWPE, with a steady-state penetration rate far below the osteolysis threshold.”

These statements are representative of the consensus that has developed in the past several years regarding HCLPE w/VE; namely that the state-of-the-art joint replacement includes the use of HCLPE w/VE [33-38].



What tests have been performed on Poly-XVE?

Mechanical property tests were performed to ASTM F2977-13 on the following samples:

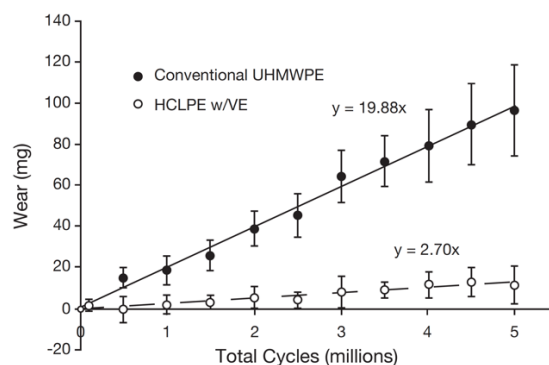
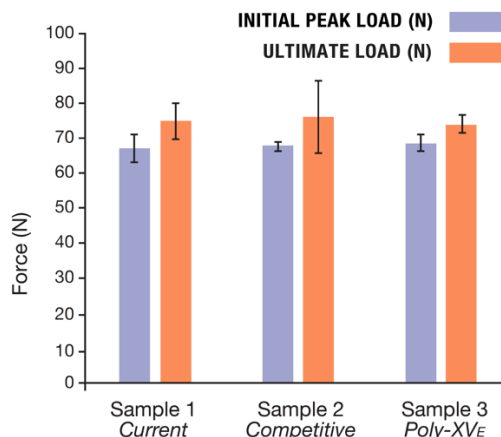
1. Sample #1: current UHMWPE (Ultra High Molecular Weight Polyethylene) gamma irradiated to 25 kGy
2. Sample #2: competitive human HCLPE (Highly Crosslinked Polyethylene) with vitamin E gamma irradiated to 100 kGy
3. Sample #3: BioMedtrix Poly-XVE (Highly Crosslinked Polyethylene with vitamin E) gamma irradiated to 125kGy

These results confirm the additional gamma radiation has not changed the mechanical properties of the Poly-XVE.

SAMPLE	INITIAL PEAK LOAD (N)	ULTIMATE LOAD (N)
1	67.1±4.1	74.8±4.9
2	67.6±1.4	75.9±10.2
3	68.6±2.3	73.9±2.4

Data courtesy of PPD Industries, Inc.

In addition, the benefits from this cross linking with reduced oxidation through the vitamin E demonstrates significantly improved wear properties both in laboratory testing and clinical follow-up in human total joint replacements.





Does highly cross-linked polyethylene with vitamin E have a place in veterinary orthopedics?

Yes.

Although polyethylene wear has not been a frequent clinical issue in veterinary total joint replacement, there remains an interest in improving shelf life of polyethylene implants and reducing long term wear in young THR patients. Provided the cost of this technology is affordable and reasonable, the product should be offered as an option.

Lab testing of the BFX® Cup (Tech Report No. 170904-1 and 180929-1) with highly crosslinked poly and Vitamin E demonstrated no issues in the assembly of the liner, impaction into polyurethane foam or in cadaver evaluations. There is no difference in surgery.

The BioMedtrix Poly-XV_E material is based on HCLPE with Vitamin E which has successful clinical outcomes in human TJR applications.



HCLPE w/VE has a more yellowish appearance due to the added Vitamin E.



Assembled BFX Cup with HCLPE w/VE Insert (post sterilization)



What will be the increased cost for BioMedtrix products using Poly- XV_E?

The cost of the material will be more expensive than conventional polyethylene. However, with sufficient quantity purchase of the raw material, the part cost increase will be less than \$100.00.

What products will be converted to Poly-XV_E?

The first product to utilize Poly-XV_E will be the BFX[®] Cup liner. All sizes will be offered with the Poly-XV_E liners as an option for the younger patients where poly wear over a long period of time could be a concern.

Other products which will be offered in Poly-XV_E will include the CFX[®] Cups, the Micro & Nano CFX Cups, the new BFX Micro & Nano Cup liners (currently in development), TKR tibial bearings and the TATE Elbow[®] radio-ulnar bearing.

Summary

BioMedtrix Poly-XV_E is a highly crosslinked polyethylene with vitamin E from validated human medical suppliers. Implants are manufactured from this material by an ISO 13485 facility specializing in the production of polyethylene implants for human orthopedic companies.

In human total joint replacements, HCLPE w/VE has become the standard material for the implant bearing surfaces when using polyethylene. It is likely become the only material available in the future as the material manufacturers have a responsibility to provide the best products based on clinical outcomes.

BioMedtrix utilizes UHMWPE that is part of FDA Master File, MAF #2795, titled "PPD Merit UHMWPE Materials."



References

1. Biomet Biomaterials Laboratory Warsaw Indiana. "The Revolutionary Second Generation, Vitamin E Stabilized Highly Crosslinked UHMWPE." Zimmer Biomet.
2. Grupp TM, et.al. Biotribology of a vitamin E-stabilized polyethylene for hip arthroplasty – Influence of artificial aging and third-body particles on wear. *Acta Biomaterialia* 10 (2014) 3068-3078.
3. Gigante, Antonio et al. "Effectiveness of Vitamin-E-Doped Polyethylene in Joint Replacement: A Literature Review." Ed. Rajshree Mootanah. *Journal of Functional Biomaterials* 6.3 (2015): 889–900. PMC.
4. Michael P. Ast, Thomas K. John, Anthony Labbisiere, Nicolas Robador, Alejandro Gonzalez Della Valle. "Fractures of a Single Design of Highly Cross-Linked Polyethylene Acetabular Liners: An Analysis of Voluntary Reports to the United States Food and Drug Administration." *The Journal of Arthroplasty*. Volume 29, Issue 6, 2014. Pages 1231-1235
5. Orhun K Muratoglu, Evan S Greenbaum, Charles R Bragdon, Murali Jasty, Andrew A Freiberg, William H Harris. Surface Analysis of Early Retrieved Acetabular Polyethylene Liners. *The Journal of Arthroplasty*. Volume 19, Issue 1, 2004. Pages 68-77
6. Plank, G. R., Estok, D. M., Muratoglu, O. K., O'Connor, D. O., Burroughs, B. R. and Harris, W. H. "Contact Stress Assessment of Conventional and Highly Crosslinked Ultra High Molecular Weight Polyethylene Acetabular Liners with Finite Element Analysis and Pressure Sensitive Film." *J. Biomed. Mater. Res.*, 80B: 1–10.
7. Zimmer Biomet white paper. "Vivacit-E Vitamin E Highly Crosslinked Polyethylene Long-Term Performance for High Demand Patients."
8. Sutula L, Collier J, Saum K, Currier B, Currier J, Sanford W, et al. The Otto Aufranc Award. Impact of gamma sterilization on clinical performance of polyethylene in the hip. *Clin Orthop*. 1995;(319):28–40.
9. Willert H, Bertram H, Buchhorn G. Osteolysis in alloarthroplasty of the hip. The role of bone cement fragmentation. *Clin Orthop*. 1990;258:108–121.
10. Willert HG, Bertram H, Buchhorn GH. Osteolysis in alloarthroplasty of the hip: The role of ultra-high molecular weight polyethylene wear particles. *Clin Orthop*. 1990;258:95–107.
11. Muratoglu OK, Kurtz S. Alternate Bearing Surfaces in Hip Replacement. In: Sinha R, editor. *Hip Replacement. Current Trends and Controversies*; New York, NY: 2002. pp. 1–46.
12. Oral E, Wannomae KK, Rowell SL, Muratoglu OK. Diffusion of vitamin E in ultra-high molecular weight polyethylene. *Biomaterials*. 2007;28:5225–5237. doi: 10.1016/j.biomaterials.2007.08.025.
13. Oral E, Muratoglu OK. Vitamin E diffused, highly crosslinked UHMWPE: a review. *Int Orthop*. 2011;35:215–223. doi: 10.1007/s00264-010-1161-y.
14. Kurtz SM, Dumbleton J, Siskey RS, Wang A, Manley M. Trace concentrations of vitamin E protect radiation crosslinked UHMWPE from oxidative degradation. *J Biomed Materials Res. Part A*. 2009;90:549–563. doi: 10.1002/jbm.a.32122.
15. Haider H, Weisenburger JN, Kurtz SM, Rimnac CM, Freedman J, Schroeder DW, Garvin KL. Does vitamin E-stabilized ultrahigh-molecular-weight polyethylene address concerns of cross-linked polyethylene in total knee arthroplasty? *J Arthroplasty*. 2012;27:461–469. doi: 10.1016/j.arth.2011.03.024.
16. Dumbleton JH, D'Antonio JA, Manley MT, Capello WN, Wang A. The basis for a second-generation highly cross-linked UHMWPE. *Clin Orthop Relat Res*. 2006;453:265–271.
17. Bracco P, Oral E. Vitamin E-stabilized UHMWPE for total joint implants: a review. *Clin Orthop Relat Res*. 2011;469:2286–2293. doi: 10.1007/s11999-010-1717-6.
18. Affatato S, Bracco P, Costa L, Villa T, Quaglini V, Toni A. In vitro wear performance of standard, crosslinked, and vitamin-E-blended UHMWPE. *J Biomed Materials Res. Part A*. 2012;100:554–560. doi: 10.1002/jbm.a.33297.
19. Collier JP, Currier BH, Kennedy FE, Currier JH, Timmins GS, Jackson SK, Brewer RL. Comparison of cross-linked polyethylene materials for orthopaedic applications. *Clin Orthop Relat Res*. 2003;414:289–304. doi: 10.1097/01.blo.0000073343.50837.03.
20. Oral E, Wannomae KK, Rowell SL, Muratoglu OK. Diffusion of vitamin E in ultra-high molecular weight polyethylene. *Biomaterials* 2007;28(35):5225-37.



21. Oral E, Wannomae KK, Kawkins NE, Harris WH, Muratoglu OK. Alpha-tocopherol doped irradiated UHMWPE for high fatigue resistance and low wear. *Biomaterials* 2004; 25(24):5515-22.
22. Devane Peter A., et.al. Highly Cross-Linked Polyethylene Reduces Wear and Revision Rates in Total Hip Arthroplasty. *J Bone Joint Surg Am* 2017; 99:1703-1714.
23. Lachiewicz Paul F, et.al. Highly-Cross Linked Polyethylene Provides Decreased Osteolysis and Reoperation at Minimum 10-Year Follow-Up. *J Arthroplasty* 31 (2016); 1959-1962.
24. Edidin AA, Pruitt L, Jewett CW, Crane DJ, Roberts D, Kurtz SM. Plasticity-induced damage layer is a precursor to wear in radiation-cross-linked UHMWPE acetabular components for total hip replacement. *Ultra-high-molecular-weight polyethylene. J Arthroplasty* 1999;14(5):616-27.
25. Mayer Constantin, et.al. Wear Kinetics of Highly Cross-Linked and Conventional Polyethylene Are Similar at Medium-term Follow-Up After Primary Total Hip Arthroplasty. *J Arthroplasty* 33 (2018); 2671-2676.
26. Oral, E.; Greenbaum, E.S.; Malhi, A.S.; Harris, W.H.; Muratoglu, O.K. Characterization of irradiated blends of -tocopherol and UHMWPE. *Biomaterials* 2005, 26, 6657–6663.
27. Digas G, Karrholm J, Thanner J, Malchau H, Herberts P. The Otto Aufranc Award. Highly cross-linked polyethylene in total hip arthroplasty: randomized evaluation of penetration rate in cemented and uncemented sockets using radiostereometric analysis. *Clin Orthop Relat Res.* 2004;429:6–16. doi: 10.1097/01.blo.0000150314.70919.e3.
28. Digas G, Karrholm J, Thanner J, Malchau H, Herberts P. Highly cross-linked polyethylene in cemented THA: randomized study of 61 hips. *Clin Orthop Relat.* 2003;417:126–138.
29. D'Antonio JA, Manley MT, Capello WN, Bierbaum BE, Ramakrishnan R, Naughton M, Sutton K. Five-year experience with crossfire highly cross-linked polyethylene. *Clin Orthop Relat Res.* 2005;441:143–150. doi: 10.1097/00003086-200512000-00024.
30. Collier JP, Currier BH, Kennedy FE, Currier JH, Timmins GS, Jackson SK, Brewer RL. Comparison of cross-linked polyethylene materials for orthopaedic applications. *Clin Orthop Relat Res.* 2003;414:289–304. doi: 10.1097/01.blo.0000073343.50837.03.
31. Jasty M, Rubash HE, Muratoglu O. Highly cross-linked polyethylene: the debate is over—in the affirmative. *J Arthroplasty.* 2005;20:55–58. doi: 10.1016/j.arth.2005.03.015.
32. G.A. Macheras et al. Survivorship of a Porous Tantalum Monoblock Acetabular Component in Primary Hip Arthroplasty With a Mean Follow-Up of 18 Years, *J Arthroplasty* 32 (2017) 3680e3684. doi.org/10.1016/j.arth.2017.06.049.
33. Rochcongar G, et.al. Reduced wear in Vitamin E-infused highly cross-linked polyethylene cups: 5-year results of a randomized controlled trial. *Acata Orthopaedica*, DOI: 10.1080/17453674.2020.18572785.
34. Michael C Wyatt, et.al. Does vitamin E highly cross-crosslinked polyethylene convey an advantage in primary total hip replacement? A systematic review and meta-analysis. *HIP International* , DOI.org/10.1177/1120700019858335. June 2019.
35. G Rochcongar, et.al. Creep and Wear in Vitamin E-Infused Highly Cross-Linked Polyethylene Cups for Total Hip Arthroplasty. *JBJS Vol. 100-A, No.2* (2018); 107-114.
36. M H Galea, et.al. Evaluation of In Vivo Wear of Vitamin E-Stabilized Highly Crosslinked Polyethylene at Five Years: A Multicentre Radiosterometric Analysis Study. *Orthopaedic Proceedings*, 2018, British Editorial Society of Bone and Joint Surgery.
37. Bitar Shareghi, et.al. Wear of Vitamin E-Infused Highly Cross-Linked Polyethylene at Five Years. *JBJS Vo. 99-A, No. 17*, September 6, 2017.

About the author:

Dr. Robert Poggie has worked in the orthopaedic industry since 1992 with experience in applied research, regulatory affairs, clinical outcomes, and medical education. Bob was instrumental in the research and development of Smith & Nephew's Oxinium and Implex's Hedrocel biomaterial (now part of Zimmer Biomet), which is now trade named Trabecular Metal. Since 2009, Bob has been an industry consultant (BioVera) for regulatory affairs, applied research, device testing, and commercialization. Prior to BioVera, Bob was a Director at Zimmer TMT, where he managed applied research, regulatory and clinical affairs. He was responsible for numerous regulatory clearances for spinal, hip, knee, and shoulder products with the US FDA and for CE Mark, as well as the training materials for prospective surgeon users and sales associates. Prior to Zimmer, Bob directed Applied Research and Regulatory Affairs for Implex Corp., which included research, university-based testing, and global regulatory approvals. He managed FDA regulated investigational studies, which included the recruitment of surgeon investigators, data compilation, and publication of results. Prior to Implex, Bob was a senior research engineer for Smith & Nephew, responsible for metallurgical and tribological research. Bob has published numerous peer reviewed papers and presented globally as invited faculty for conferences and education courses. Bob earned a BE in Mechanical Engineering, and MS and PhD degrees in Materials Science & Engineering, all from Vanderbilt University in Nashville, TN.



9 Whippany Road, Suite B2-7 | Whippany, New Jersey 07981 | telephone 973.331.7800

biomedtrix.com